

REMARKS:

In the Office Action dated September 29, 2009, claims 1-3, 5-12, 15, 16, and 18-24, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1-3, 5-12, 15, 16, and 18-24 remain in this application and claims 4, 13-14, and 17 have been canceled.

Claims 1-3, 15, 16 and 20-23 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680). As discussed in applicant's prior response, Kiliaan's preparation is not a solid matrix. This rejection appears to be based on example 1 of Kiliaan. Example 1 in Kiliaan is a liquid formulation and does not disclose a wax component. Example 1 in Kiliaan contains 70 wt. % liquid components (DHA, EPA, phospholipids and vitamin E; in total of 575 mg) and thus the matrix would be liquid. This is discussed in Dirk Cremer's and Elisabeth Markl's previously submitted declarations. della Valle was cited for the disclosure of a wax component. The only disclosure of a wax in della Valle is the bees wax in example 5 which is directed to a gelatinous capsule. The beeswax is the only solid component in the gelatinous capsule formulation and makes up only 0.25 wt. % of the formula. Since 99.75% of the components are liquid, della Valle's formulation would not be a solid matrix. Applicants respectfully point out that neither Kiliaan or della Valle individually or in combination suggest or disclose how to stabilize a matrix containing phosphatidyl serine and phosphatidyl choline, how to encapsulate a solid matrix containing these compounds, or that the stability of phosphatidyl serine and phosphatidyl choline can be significantly improved. As discussed in the present application on page 2, the prior art phosphatidyl serine and phosphatidyl choline

formulations in soft capsules are not sufficiently stable and the prior art formulation of phosphatidyl serine embedded in a hard fat cannot be encapsulated. The present inventors have surprisingly found that the claimed matrix is stable and can be encapsulated. The combination of Kiliaan and della Valle does not suggest such a formulation as both Kiliaan (example 1) and della Valle (example 5) disclose liquid formulations. Though Kiliaan includes some solid forms such as powder and paste as possible forms for the preparation, there is no disclosure and specifically no examples suggesting that the preparation can be stabilized and encapsulated by using a solid matrix with the components and ratios recited in the present claims. In contrast to the cited prior art, the present matrix is solid, stable and encapsulated. Claim 1 has been amended in order to clarify that the matrix is solid. Claims 20 and 22 currently recite that the matrix is solid or paste like at room temperature and claim 21 indicates that the solid portion of triglyceride is >80% at 23°C. Applicants contend that the combination of Kiliaan and della Valle does not suggest that it is possible or desirable to prepare a stable, solid matrix containing phosphatidyl serine and phosphatidyl choline, which can be encapsulated, and does not suggest the components and ratios recited in the present claims which are necessary to produce such a matrix. In view of the above discussion, applicants request that this rejection be withdrawn.

Claims 1-3, 5, 15, 16, 19 and 20-23 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680) further in view of Patel (US 6,294,192). Patel was cited for the disclosure of solubilizers such as polyethylene glycol. Patel is directed to a pharmaceutical composition for delivering hydrophobic agents. Patel's preparation is intended to form an aqueous dispersion after

administration and can be administered in the form of a solid dispersion (col. 26, lines 25-34). Patel does not suggest or disclose that it is possible or desirable to prepare a stable, solid matrix containing phosphatidyl serine and phosphatidyl choline, which can be encapsulated, and does not suggest the components and ratios recited in the present claims which are necessary to produce such a matrix. Therefore, Patel does not cure the above discussed deficiencies in Kiliaan and della Valle and applicants request that this rejection be withdrawn.

Claims 1, 6-12, 18, 22 and 24 were rejected under 35 USC §103(a) as unpatentable over Kiliaan (WO 0184961) in view of della Valle (US 4,595,680) further in view of Winston Jr. (US 5,342,626). Winston Jr. was cited for the disclosure of encapsulating materials such as gelatin and nongelatin polymers. Winston Jr. does not suggest or disclose that it is possible or desirable to prepare a stable, solid matrix containing phosphatidyl serine and phosphatidyl choline, which can be encapsulated, and does not suggest the components and ratios recited in the present claims which are necessary to produce such a matrix. Therefore, Winston Jr. does not cure the above discussed deficiencies in Kiliaan and della Valle and applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 1-3, 5-12, 15, 16, and 18-24 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By Monica Chin Kitts/
Monica Chin Kitts
Attorney for Applicant
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040

MCK/cb